In paragraph 2 of the Office Action, claims 1-19 were rejected under 35U.S.C.§103(a) as being unpatentable over Balazs et al. (Balazs) in view of Halpern et al. (Halpern)

Reconsideration is requested.

The Examiner commented: "*Balazs et al. disclose the covalent bonding of hyaluronic acid to polyurethane and the use of such materials in medical applications. See example 3*".

It is requested that the Examiner consider that in Example 3, col. 2, line 55 of Balazs, it was reported that a polyurethane film was coated with a solution of hyaluronic acid sodium salt, so that "*incorporation of Na-HA occurred by covalent bonding to the polyurethane surface*" (Balazs, col. 3, lines 8-10). The claims of the present application point out that the polyurethane is covalently bound to sulphated hyaluronic acid. The sulphated hyaluronic acid is obtained by reacting the hyaluronic acid derivative with a polyurethane solution (see present specification, Examples 1-3, 6 and 7). Therefore, according to the present invention, the resulting polyurethane is modified by incorporation of the hyaluronic acid derivative not only on the surface but also in bulk, because the reaction occurs between the two reagents in solution.

The polyurethane resulting from Balazs' Example 3 is on the contrary modified only on the surface, because the reaction occurs between a hyaluronic acid solution and a polyurethane film.

The difference between the two resulting materials is substantial: in fact, the amount of hyaluronic acid derivative bound to the surface is low, whereas it greatly

increases through a bulk modification. When the hyaluronic acid derivative is covalently bound to polyurethane both in bulk and on the surface, as in the present invention, the hyaluronic acid derivative which is not on the surface influences the anticoagulant properties of the material when this material is placed in hydrophilic environments, such as normal saline.

The Applicant has discovered that the hydrophilic component of the present modified polyurethane, when placed in a hydrophilic environment, i.e. the hyaluronic acid derivative, migrates to the surface, thus increasing its concentration at the biological system/material interface.

This modification of the structure of the claimed material's surface, as a function of the environment, is evidence that a substantial amount of the hyaluronic acid sulfate is on the surface when the material comes into contact with blood, and this provides enhanced properties, as measured by platelet adhesion, coagulation time, etc. (see present application, Examples 9-13).

In this regard, it is requested that the Examiner note what was reported at the end of Example 11, page 17 of the present application: "*The anticoagulant activity occurs on the side of the film which is in contact with the glass because the polar environment causes the sulfated hyaluronic acid group to be exposed on the surface, while different results are observed on the side of which is in contact with the air*".

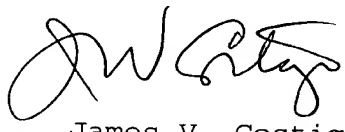
These results could not be predicted from Balazs, either alone or in combination with Halpern. The Halpern patent makes no reference to the bulk modification of polyurethanes or similar polymers by the covalent binding of the polyurethanes to sulfated hyaluronic acid and derivatives thereof or other sulfated polysaccharides.

As to Halpern, the modification of the plastics described therein occurs only on their surface, which is coated by polysaccharides.

New claims 20-36 have been added to point out the invention using product by process terminology. The newly added claims 20-36 find complete support in the originally filed description and claims; in particular, the description of the process for obtaining the present products in claim 20 is supported by the originally filed Examples 1-3, 6 and 7.

Early and favorable action is earnestly requested.

Respectfully submitted,



James V. Costigan
Registration No.: 25,669

Hedman & Costigan, P.C.
1185 Avenue of the Americas
New York, N.Y. 10036
(212) 302-8989